

AMENDMENTS TO THE CLAIMS

1. (Withdrawn) A reagent comprising: any one of cells, viral particles, organelles, parasites, cells comprising organelles, cells comprising viral particles, cells comprising parasites, cells comprising bacterial cells and any combination thereof, said cells, viral particles, organelles or parasites comprising at least one nucleic acid sequence serving as an internal control (IC) target for nucleic acid testing (NAT) assay; wherein said reagent is suitable to be added to a test sample undergoing sample preparation to release, concentrate and/or purify nucleic acids and amplification and/or detection of nucleic acids so as to be used to verify:

(i) the efficiency of sample preparation; and

(ii) the efficiency of nucleic acid amplification and/or detection.

2. (Withdrawn) The reagent as defined in claim 1, wherein said cells is selected from bacteria, fungi or parasites, eukaryotic cells, or plant cells.

3. (Withdrawn) The reagent as defined in claim 1, wherein said cells is selected from bacterial cells, or bacterial spores.

4. (Withdrawn) The reagent as defined in claim 3, wherein said cells are E. coli cells or said spores are Bacillus spores.

5. (Withdrawn) The reagent as defined in claim 4, wherein said spores are Bacillus globigii spores.

6. (Withdrawn) The reagent as defined in claim 1, wherein said organelle is a mitochondria or a chloroplast.

7. (Withdrawn) The reagent as defined in claim 1, wherein said IC target nucleic acid sequence is on a cloning vector.

8. (Withdrawn) The reagent as defined in claim 7, wherein said IC target nucleic acid sequence is on a plasmid vector.

9. (Withdrawn) The reagent as defined in claim 1, wherein said nucleic amplification method comprises PCR.

10. (Withdrawn) The reagent as defined in claim 1, wherein said IC target nucleic acid sequence is a nucleic acid sequence of clinical, environmental, alimentary or human origin.

11. (Withdrawn) The reagent as defined in claim 1, wherein said IC target nucleic acid sequence is of microbial origin.

12. (Withdrawn) The reagent as defined in claim 1, wherein said test sample comprises a sample of clinical, environmental, or alimentary origin.

13. (Withdrawn) The reagent as defined in claim 1, wherein said test sample comprises a vaginal/anal or a nasal swab.

14. (Withdrawn) The reagent as defined in claim 1, wherein said sample preparation method comprises:

(i) concentration and/or purification of cells, viral particles, organelles, parasites or cells comprising organelles and/or viral particles cells and/or parasites and/or bacterial cells,

(ii) lysis of cells, viral particles, organelles or cells comprising organelles and/or viral particles and/or parasites and/or bacterial cells,

(iii) nucleic acid extraction,

(iv) elimination, neutralization and/or inactivation of NAT inhibitors, and/or

(iv) nucleic acid concentration and/or purification.

15. (Currently amended) A method for verifying the efficiency of sample preparation of test sample nucleic acids and the performance of nucleic acid amplification and detection practiced on a test sample after its preparation, said method comprising:

(i) providing an internal control reagent selected from the group consisting of cells, ~~organelles~~, parasites, cells comprising organelles, cells comprising viral particles, cells comprising parasites, cells comprising bacterial cells and any combination thereof, said internal control reagent having at least one internal control (IC) nucleic acid target sequence therein, wherein said internal control reagent is an internal control for the release, amplification, and detection of a nucleic acid from said test sample;

(ii) adding said internal control reagent into said test sample;

(iii) submitting said test sample with said added internal control reagent to a sample preparation procedure in order to release both said nucleic acid from said test sample and said IC nucleic acid target sequence from said internal control reagent; and

(iv) submitting a product from said sample preparation procedure to amplification and detection for the amplification and detection of both said IC nucleic acid target sequence and said nucleic acid of the test sample, wherein detection of said IC nucleic

acid target sequence is indicative of both efficient sample preparation and performance of nucleic acid amplification.

16. (Previously presented) The method as defined in claim 15, further comprising

(v) comparing the amplification and detection performed in iv) to the amplification and detection performed with a control reaction to evaluate the efficiency of the sample preparation and the performance of the nucleic acid amplification and detection practiced on said test sample and reagent.

17. (Currently amended) The method of claim 15, wherein said sample preparation procedure comprises concentrating and/or purifying cells, ~~viral particles,~~ organelles or cells comprising organelles, and/or viral particles prior to lysis.

18. (Previously presented) The method of claim 15, wherein said cells are selected from bacteria, fungi or parasites.

19. (Previously presented) The method of claim 15, wherein said cells are *E. coli* cells.

20. (Previously presented) The method of claim 15, wherein said cells are bacterial spores.

21. (Previously presented) The method of claim 20, wherein said cells are *Bacillus* spores.

22. (Previously presented) The method of claim 21, wherein said cells are *Bacillus globigii* spores.

23. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is on a cloning vector.

24. (Previously presented) The method of claim 23, wherein said IC nucleic acid target sequence is on a plasmid vector.

25. (Previously presented) The method of claim 15, wherein said nucleic acid amplification method is PCR.

26. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is nucleic acid sequence of clinical, environmental, alimentary or human origin.

27. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is a nucleic acid sequence of microbial origin.

28. (Previously presented) The method of claim 15, wherein the said test sample is a sample of clinical, environmental or alimentary origin.

29. (Previously presented) The method of claim 15, wherein said test sample comprises a vaginal/anal or a nasal swab.

30. (Currently amended) The method of claim 15, wherein said sample preparation procedure comprises

- (i) concentration and/or purification of cells, ~~organelles~~ or cells comprising organelles and/or viral particles,
- (ii) lysis of cells, ~~organelles~~ or cells comprising organelles and/or viral particles,
- (iii) nucleic acid extraction,
- (iv) elimination, neutralization and/or inactivation of nucleic acid testing (NAT) inhibitors, and/or
- (v) nucleic acid concentration and/or purification.

31. (Previously presented) The method of claim 15, wherein said internal control reagent is a spore which serves as a model cell to monitor the efficiency of sample preparation and amplification and detection.

32. (Currently amended) A method for verifying the efficiency of sample preparation of test sample nucleic acids and the performance of nucleic acid amplification and detection practiced on a test sample after its preparation, said method comprising:

- (i) providing a an internal control reagent selected from the group consisting of a cell, an ~~organelle~~, a parasite, a cell comprising an organelle, a cell comprising a viral particle, a cell comprising a parasite, a cell comprising a bacterial cell and any combination thereof, said internal control reagent having at least one internal control (IC) nucleic acid target sequence therein, wherein said internal control reagent is an internal control for the release, amplification and detection of a nucleic acid from said test sample;
- (ii) adding said internal control reagent into said test sample;
- (iii) submitting said test sample with said added internal control reagent to a nucleic acid amplification procedure in order to release both said nucleic acid from said

test sample and said IC nucleic acid target sequence from said internal control reagent;
and

(iv) submitting a product from said amplification procedure to further amplification or detection for the amplification or detection of both said IC nucleic acid target sequence and said nucleic acid of the test sample, wherein detection of said IC nucleic acid target sequence is indicative of both efficient sample preparation and performance of nucleic acid amplification.

33. (Currently amended) The method of claim 16 wherein said sample preparation procedure comprises concentrating and/or purifying cells, ~~viral particles, organelles~~ or cells comprising organelles; and/or viral particles prior to lysis.

34. (Previously presented) The method of claim 16, wherein said cells are selected from bacteria, fungi or parasites.

35. (Previously presented) The method of claim 16, wherein said cells are *E. coli* cells.

36. (Previously presented) The method of claim 16, wherein said cells are bacterial spores.

37. (Previously presented) The method of claim 36, wherein said cells are *Bacillus* spores.

38. (Previously presented) The method of claim 37, wherein said cells are *Bacillus globigii* spores.

39. (Previously presented) The method of claim 16, wherein said IC nucleic acid target sequence is on a cloning vector.

40. (Previously presented) The method of claim 39, wherein said IC nucleic acid target sequence is on a plasmid vector.

41. (Previously presented) The method of claim 16, wherein said nucleic acid amplification method is PCR.

42. (Previously presented) The method of claim 16, wherein said IC nucleic acid target sequence is nucleic acid sequence of clinical, environmental, alimentary or human origin.

43. (Previously presented) The method of claim 16, wherein said IC nucleic acid target sequence is a nucleic acid sequence of microbial origin.

44. (Previously presented) The method of claim 16, wherein the said test sample is a sample of clinical, environmental or alimentary origin.

45. (Previously presented) The method of claim 16, wherein said test sample comprises a vaginal/anal or a nasal swab.

46. (Currently amended) The method of claim 16, wherein said sample preparation method comprises

(i) concentration and/or purification of cells—~~organelles~~ or cells comprising organelles and/or viral particles,

(ii) lysis of cells, organelles or cells comprising organelles and/or viral particles,

(iii) nucleic acid extraction,

(iv) elimination, neutralization and/or inactivation of nucleic acid testing (NAT) inhibitors, and/or

(v) nucleic acid concentration and/or purification.